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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/607,580

06/26/2003

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EXAMINER

HANLEY, SUSAN MARIE

ART UNIT

PAPER NUMBER

1651

MAIL DATE

DELIVERY MODE

10/28/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/607,580	<b>Applicant(s)</b> BERETTA ET AL.	
	<b>Examiner</b> SUSAN HANLEY	<b>Art Unit</b> 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 18-22, 24, 25, 27-32 and 34-41 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 32 and 34-41 is/are allowed.
- 6) ☒ Claim(s) 18, 20-22, 24, 25, 27, 28, 30 and 31 is/are rejected.
- 7) ☒ Claim(s) 29 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Claims 18, 20-22, 24, 25, 27-32 and 34-41 are under examination.

#### ***Withdrawal of Rejections***

The rejections not explicitly restated below are withdrawn due to Applicant's response in the amendment filed 12/31/07.

#### ***New Grounds of Rejection***

##### ***Double Patenting***

Claims 24, 25, 27, 28, 30 and 31 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3, 4, 5, 6 and 11-13 of U.S. Patent No. 6,979,307.

Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1 and 11 of '307 are drawn to a system for preparing an autologous solid-fibrin web wherein the system comprises sealed primary and secondary containers. The sealed primary container comprises a separation medium that can be a gel, a float device or beads and the secondary container comprises a coagulant. The system also comprises a transfer means, such as a cannula. The specification of '307 defines a gel as one that is thixotropic, capable of density-gradient separation of the plasma and the blood cells. The disclosure of a thixotropic gel by '307 meets the limitations in the last paragraph of instant claim 24 because the ability of the gel to direct or prevent movement of particles at during a given centrifuge speed is an inherent property of the thixotropic gel. Thus, '307 is a specie of the instant claims because '307 claims two containers separated by a thixotropic gel wherein the second

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container holds a coagulant. In the absence of disclosure to the contrary by the claims of '307, the ordinary artisan could reasonably assume that the circumferences of the chambers are the same. The instant claims have open transitional language ("comprising") which allows for the prior art device to comprise additional features that are not instantly claimed, such as a transfer means and pressurized containers. Claims 5 and 13 of '307 name therapeutic agents contained in the secondary container as in instant claims 30 and 31. The system of '307 is interpreted as device because the claim language of '307 is directed to describing an apparatus/device and not the method of using it. It is noted that the MPEP 804 notes that it is appropriate to use the specification as a dictionary for claim interpretation:

When considering whether the invention defined in a claim of an application is an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as prior art. This does not mean that one is precluded from all use of the patent disclosure. The specification can always be used as a dictionary to learn the meaning of a term in the patent claim. In *re Boylan*, 392 F.2d 1017, 157 USPQ 370 (CCPA 1968). Further, those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. In *re Vogel*, 422 F.2d 438, 441-42, 164 USPQ 619, 622 (CCPA 1970). The court in *Vogel* recognized "that it is most difficult, if not meaningless, to try to say what is or is not an obvious variation of a claim," but that one can judge whether or not the invention claimed in an application is an obvious variation of an embodiment disclosed in the patent which

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provides support for the patent claim. According to the court, one must first “determine how much of the patent disclosure pertains to the invention claimed in the patent” because only “[t]his portion of the specification supports the patent claims and may be considered.” The court pointed out that “this use of the disclosure is not in contravention of the cases forbidding its use as prior art, nor is it applying the patent as a reference under 35 U.S.C. 103, since only the disclosure of the invention claimed in the patent may be examined.”

Claims 18 and 20-22 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3, 4, 5, 6 and 11-13 of U.S. Patent No. 6,979,307 in view of Jahn (US 5,275,731; previously cited) and Smith (US 4,957,638).

The disclosure of claims 1, 3, 4, 5, 6 and 11-13 of U.S. Patent No. 6,979,307 is discussed supra.

The claims of the '307 patent does not disclose that the separation medium comprises a filter.

Jahn discloses a device for separating plasma from a blood sample. The separation medium is a filter that allows the plasma to move downward in the centrifuge tube while preventing the ability of the heavier particle to follow suit.

Smith teaches that it is desirable to combine a thixotropic gel barrier (that separates blood components) with a filter to overcome the problems relating to the absorption of water by the gel. (col. 15, lines 40-60).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add a filter to the thixotropic barrier in the system of '307. The ordinary artisan would have been motivated to do so because Smith teaches that the addition of a filter to a thixotropic gel prevents problems with water absorption by the gel. The ordinary artisan would have had a reasonable expectation that the combination of a thixotropic gel and filter would cause plasma to move downward during centrifugation while preventing heavier particles from doing the same because Jahn demonstrated that filters can perform this function. Thus, the ordinary artisan could reasonable expect that the combination of two materials (thixotropic gel and a filter) that have the same function could be combined for said purpose.

Claims 24, 25, 27, 28, 30 and 31 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 7, 9 and 10 of copending Application No. 11/284,584. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 7 of '584 is drawn to a system for preparing an autologous solid-fibrin web wherein the system comprises sealed primary and secondary containers. The sealed primary container comprises a separation medium that can be a gel, a float device or beads and the secondary container comprises a coagulant. The specification of '584 defines a gel as one that is thixotropic, capable of density-gradient separation of the plasma and the blood cells. The disclosure of a thixotropic gel by '307 meets the limitations in the last paragraph of instant claim 24 because the ability of the gel to prevent movement of

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particles at during a given centrifuge speed in an inherent property of the thixotropic gel.

Claim 7 of '584 also recites a transfer means. Thus, '584 is a specie of the instant claims because '584 claims two containers separated by a thixotropic gel wherein the second container holds a coagulant. The instant claims have open transitional language ("comprising") which allows for the prior art device to comprise additional features that are not instantly claimed, such as a transfer means. In the absence of disclosure to the contrary by the claims of '584, the ordinary artisan could reasonably assume that the circumferences of the chambers are the same. The instant claims have open transitional language ("comprising") which allows for the prior art device to comprise additional features that are not instantly claimed, such as a transfer means and pressurized containers. The system of '584 is interpreted as device because the claim language of '584 is directed to describing an apparatus/device and not the method of using it. It is noted that the MPEP 804 notes that it is appropriate to use the specification as a dictionary for claim interpretation *supra*.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 18 and 20-22 are provisional rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 7, 9 and 10 of copending Application No. 11/284,584 in view of Jahn (US 5,275,731; previously cited) and Smith (US 4,957,638).

The disclosure of the claims of '584, Jahn and Smith are discussed *supra*.

The claims of the '584 patent do not disclose that the separation medium comprises a filter.

Jahn discloses a device for separating plasma from a blood sample. The separation medium is a filter that allows the plasma to move downward in the centrifuge tube while preventing the ability of the heavier particle to follow suit.

Smith teaches that it is desirable to combine a thixotropic gel barrier (that separates blood components) with a filter to overcome the problems relating to the absorption of water by the gel. (col. 15, lines 40-60).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add a filter to the thixotropic barrier in the system of '584. The ordinary artisan would have been motivated to do so because Smith teaches that the addition of a filter to a thixotropic gel prevents problems with water absorption by the gel. The ordinary artisan would have had a reasonable expectation that the combination of a thixotropic gel and filter would cause plasma to move downward during centrifugation while preventing heavier particles from doing the same because Jahn demonstrated that filters can perform this function. Thus, the ordinary artisan could reasonable expect that the combination of two materials (thixotropic gel and a filter) that have the same function could be combined for said purpose.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.



***Allowable Subject Matter***

Claim 29 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN HANLEY whose telephone number is (571)272-2508. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susan Hanley/  
Examiner, Art Unit 1651

/Sandra Saucier/  
Primary Examiner, Art Unit 1651